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1609

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicants: | Amjad Ali, et al. | | |
| Serial No.: | 10/544,899 | Case 21284P | Art Unit: 1609 |
| Filed: | August 8, 2005 | | |
| For: | SELECTIVE NON-STEROIDAL GLUCOCORTICOID RECEPTOR MODULATORS | | Examiner: Havlin, Robert H. |

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT
AND
SUBMISSION OF SUPPLEMENTAL DECLARATION
PURSUANT TO 37 CFR 1.67

Sir:

This communication is in response to the restriction requirement dated February 20, 2007, setting forth a shortened statutory period for response ending March 20, 2007. Reconsideration of the restriction requirement and allowance of the above-captioned patent application are respectfully requested. This application relates to selective non-steroidal glucocorticoid receptor modulators.

Claims 1 to 21 are currently pending in the application. The Examiner has required restriction of Claims 1 to 21 and an election of one of **Group I** to **Group VI** as outlined in the Restriction Requirement dated February 20, 2007. **Group I** is hereby elected with traverse. Applicants also hereby elect the specie of Example 1 (structure shown at page 38), with traverse. Inasmuch as the Examiner requires election of a single disease to be treated, Applicants elect rheumatic disorders, such as rheumatoid arthritis.

Applicants respectfully request reconsideration of the restriction requirement with respect to Claims 1 to 21 and submit that these claims satisfy the unity of invention requirement because the groups are properly linked to form a single general inventive concept. As outlined in M.P.E.P. § 1893.03(d), a group of inventions is considered linked to form a single general inventive concept when there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression "special technical feature" is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.

With respect to "Markush Practice," Annex B of the PCT Administrative Instructions sets forth the standard of unity of invention as follows:

(f) "Markush Practice." The situation involving the so-called "Markush practice" wherein a single claim defines alternatives (chemical or non-chemical) is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) all alternatives have a common property or activity, and*
- (B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or*
- (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.*

(ii) In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may

be a single component or a combination of individual components linked together.

In the instant claims, the special technical feature is the common structure embodied in Formula I. All compounds share this significant common chemical structure which occupies a large portion of their structures. The claimed compounds also possess the same utility as glucocorticoid receptor modulators and for treating diseases or conditions mediated by that receptor. As such, unity of invention is present.

On page 2 of the Restriction Requirement, the Examiner alleges that the core of Formula I fails to make a contribution over the prior art. Applicants respectfully submit the Examiner's analysis is incorrect. The PCT Administrative Instructions clearly state that for situations involving Markush practice the special technical features as defined in Rule 13.2 shall be considered to be met when the alternatives are of a similar nature. A Markush grouping of chemical compounds shall be regarded as being of similar nature when all alternatives have a common property and there is a significant structural element shared by all the alternatives. The term "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. Thus, an analysis as to whether the commonly shared structure constitutes a structurally distinctive portion in view of the prior art would only be required in the latter case. Since the instant claims are directed to compounds that share a common chemical structure that occupies a large portion of their structures, an analysis under the second part is not required.

Applicants acknowledge the Examiner's indication that withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder pursuant to M.P.E.P. § 821.04.

Applicants also submit herewith a Supplemental Declaration executed by the inventor Christopher F. Thompson to correct the **residence city and state** for this inventor in the earlier filed Declaration.

Serial No.: 10/544,899
Case No.: 21284P
Page 4

Applicants respectfully request reconsideration and withdrawal of the requirement for restriction. Applicants submit that the application is in condition for allowance and passage thereto is earnestly requested. Any additional fees required in connection with this Response may be taken from Merck Deposit Account No. 13-2755. The Examiner is invited to contact the undersigned attorney at the telephone number provided below if such would advance the prosecution of the case.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.
By Larry Reynolds Date 3/14/07

Date: March 14, 2007

Respectfully submitted,

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